K081279

JAN 23 2009

510(k) Summary

Submitter's Information	Joseph J Arbour Transfer Technology 37822 Oxford Drive Murrieta, CA 92562 Phone 951-677-0631 Fax 951-677-0631
Date of Preparation	May 6, 2008
Proprietary Name	PRO-TECH Delivery System Electrodes
Common Name	Neurostimulation Electrodes
Classification Name	Electrodes, Cutaneous
Predicate Device	K000870 (Katecho Inc) K970426 (Axelgaard Manufacturing) K875284 (Medtronic Inc)
Description of Device	Electrodes, Cutaneous
Intended Use	The Transfer Technology PRO-TECH Delivery System electrodes are intended for use as a disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator Transfer Technology's reusable electrodes are designed and intended to be used with marketed Electrical Stimulators, i e TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), and MANS (Muscle and Neurological Stimulators)
Technological Comparison	The Transfer Technology PRO-TECH Delivery System electrodes exhibit technological characteristics that are substantially equivalent to those of the predicate device, as determined by both component usage and physical testing
Labeling Comparison	The labeling of Transfer Technology PRO-TECH Delivery System electrodes substantially equivalent to those of the predicate devices
Device Description	Transfer Technology reusable neurostimulator electrodes are laminated flexible materials widely used in this application Top layer Vinyl tape or non-woven fabrics with biocompatible adhesive Second layer Grade "A" pure tin or electrically conductive carbon with Ag or Ag/AgCl Third layer 125" flexible vinyl tape with biocompatible adhesive laminated around the outer perimeter of electrode Patient layer Conductive hydrogel Amgel AG703

Device Description (continued)	Lead Wire Constructed of a silicone-insulated stainless steel yarn wire with a standard 080" recessed female contact crimped and then insulated to one end By design, the insulated contact prevents the conductive connection to earth or hazardous voltages as required in IEC 60601-1 Subclause 56 3(c) Wire assembly is incompliance with FDA performance standard 21 CFR Part 898
Non-clinical Testing	The critical components used in Transfer Technology PRO-TECH Delivery System electrodes (Amgel AM703 K983741) are the same as used in the predicate devices Therefore there is no reason to believe that the Transfer Technology PRO-TECH Delivery System electrodes will perform any different than the predicate device
Clinical Testing	Not Applicable
Packaging	Electrodes are stored in a 2-mil poly re-sealable bag to comply with the shelf life specifications of the hydrogel manufacturer Labeling is compliant to 21CFR Part 801
Conclusion	The Transfer Technology PRO-TECH Delivery System electrodes are substantially equivalent to those of the submitted predicate devices and any difference between the devices do not pose new questions of safety and effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Transfer Technology
% Mr Joseph J Arbour
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Re K081279
Trade/Device Name PRO-TECH Delivery System Electrodes
Regulation Number 21 CFR 882 1320
Regulation Name Cutaneous electrode
Regulatory Class II
Product Code GXY
Dated November 17, 2008
Received November 17, 2008

Dear Mr Arbour

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Mark N Melkerson

Mark N Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K081279

Device Name PRO-TECH Delivery System Electrodes

Indications For Use The Transfer Technology PRO-TECH Delivery System electrodes are intended for use as a disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator Transfer Technology's reusable electrodes are designed and intended to be used with marketed, Electrical Stimulators, i e TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), and MANS (Muscle and Neurological Stimulators)

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM 1/23/2009

Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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